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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,198	09/10/2001	Alastair Campbell Agnew Glen	2602-1-001	3975

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
936,198	GLEW et al
Examiner	**Group Art Unit**
SAUNDERS	164

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-33 is/are pending in the application.

Of the above claim(s) 27-33 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1-33 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Claims 1-33 are pending.

Applicant's election with traverse of Group I (claims 1-26) in Paper No. filed 10/29/03 is acknowledged. The traversal is on the ground(s) that proteins of Group II and antibodies of Group III involve duplicate searches within the same class as the assay methods of Group I. This is not found persuasive because firstly, the searches are not co-extensive. The search for the antigens and the antibodies would fall, at the least, within separate subclasses of class 530 (350 and 388.26, respectively). Since the protein appears to be an enzyme a search would also be required in class 435 subclass 198. In addition to separate classifications within the US classification system, different literature searches would be required. In the era of monoclonal antibodies, numerous antibodies have been known prior to any characterization of their cognate antigens. Secondly, besides the different searches required for prior art patents or publications, there would be numerous other issues requiring consideration for the examination of Group II and III with Group I. Examination of Group II would raise a conundrum concerning written description (possession), which would require extensive examination. Examination of Group III would raise issues pertaining to prior sale/use, since the antibodies were previously commercially available. Thus examination of these two additional Groups would add both excessive search and examination burdens on the office, in addition to the search and examination of 112 issues pertaining to the assays of Group I. The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: at page 8, line 11 "sepharose" should begin with a capital.

Appropriate correction is required.

Claims 3-4 are objected to because of the following informalities: claims 3-4 end without a period. Appropriate correction is required.

Claims 1, and 16-17 are objected to because of the following informalities: each of these claims fails to comply with 37 CFR 1.75 (i) by virtue of not indenting each of the recited active verb steps. Appropriate correction is required.

Claims 2—7 and 9-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "highly unsaturated" in claims 2-7 is a relative term which renders the claim indefinite. The modifier "highly" is indefinite because, while applicant defines "highly unsaturated fatty acids" as "all fatty acids released by action of the type IV cPLA2 enzyme" (page 4, lines 25-26), this definition itself is indefinite. It is not clear that the art recognizes any limit as to the degree of unsaturation of the fatty acids released by the action of the type IV cPLA2 enzyme. Applicant appears to be defining "highly unsaturated" in terms of an enzyme yielding fatty acids, rather than in terms of a clearly recognizable structural feature of fatty acids. The term "highly" unsaturated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 11 "concentration is increased" is indefinite because it is not clear what quantity this concentration is compared against.

In claims 14-15 "the type IV cPLA2 protein" lacks antecedent basis. It is suggested that applicant insert –protein—after "(cPLA2)" in claim 1.

In claims 16-17, 19-21, 24 and 26 "detecting" and "are detected" are unclear because base claim 1 recites "examining" not "detecting" in the steps recited after "comprising."

In claim 17 "the other blood components" lack antecedent basis.

In claim 17, it is not clear how the steps of "separating", "disrupting" and "detecting" fit into the sequence of the "obtaining" and "examining" steps of base claim 1.

In claim 26 "substrate assay" is unclear. Does this use a solid substrate or an phospholipase substrate?

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an assay of type IV cPLA2 or an immunologically homologous protein in or on RBCs, in the case in which the RBCs have been isolated from whole blood, does not reasonably provide enablement for such an assay in the case in which the RBCs have not been isolated from whole blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant has disclosed (page 2, lines 25+) that PLA2 enzyme activity has been found in plasma. Applicant has also disclosed page 1, lines 29+) that type IV cPLA2 has been

found in monocytes and platelets. Since plasma, monocytes and platelets are all included in any whole blood sample, one of skill would reasonably expect that the presence of PLA2/cPLA2 in these components would confound detection of such in or on RBCs.

Claims 1-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an assay for type IV cPLA2 or an immunological homologue thereof by an immunoassay that employs an antibody against type IV cPLA2, does not reasonably provide enablement for such an assay that does not employ an antibody against type IV cPLA2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The assay requires that one be able to detect type IV cPLA2 or a protein immunologically homologous thereto.

Applicant has indicated (page 2, lines 25+) that assays for enzyme substrate activity (as encompassed by all rejected claims and specifically recited in instant claim 26) do not distinguish the type of PLA2 being detected. Therefore, one of skill would not expect that an assay not employing an antibody against type IV cPLA2 would be capable of distinguishing type IV cPLA2 among any other types of PLA2 present in a sample.

Additionally, by requiring that the assay method detect "a protein immunologically homologous to type IV cPLA2", applicant is claiming an assay that would require use of

an antibody to type IV cPLA2. Note that the term "immunologically homologous" conveys the concept that any such protein is defined as one that is immunologically cross-reactive with type IV cPLA2. As such, detection of the "immunologically homologous" protein requires the use of an antibody to type IV cPLA2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 16-18 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Filimonkova (RU 200509).

RU '509 teaches a method of diagnosis in which an erythrocyte (RBC) lysate is assayed (enzyme substrate assay) for the level of PLA2. See especially page 2 of translation. The taught assay is consistent with what is recited in instant claims 1 and 26. While applicant recites in claim 1, that the claimed assay is intended to detect type IV cPLA2, rather than generic PLA2, the examiner has noted supra, in 112 enablement rejections, that the claims are broad enough to encompass assays which to not enable the particular detection of type IV cPLA2, as apposed to generic PLA2. Therefore citation of RU '509 is proper.

From what is disclosed at page 2 of the translation, it is clear that claims 16-18 are anticipated since the erythrocytes of RU '509 are lysed, prior to detection of the phospholipase activity.

On attached form 1449, lined-through references are not locatable in IFW images.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunder/tgd

February 11, 2004

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644